

## REMARKS

### **1. *Claim Rejection Under 35 U.S.C. § 112***

Claims 1-22, 27, 28, and 31-33 stand rejected under 35 U.S.C. §112 (first paragraph). In response, Applicant has amended each of independent claims 1, 24, 27, and 31, as indicated above, to include subject matter that is properly enabled by the specification. Specifically, applicant has amended these claims to indicate that the present invention comprises a method for preventing and/or inhibiting liver damage and cancer specifically caused by the effects of carbon tetrachloride within a patient. As such, applicant respectfully requests that this rejection be withdrawn.

### **2. *Claim Rejection Under 35 U.S.C. § 103***

Claims 1-22 and 24-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Japanese Pat Application No. 08217686 A (hereinafter “JP ‘686”). In response, applicant submits that JP ‘686 does not a method of inhibiting hepatotoxin-induced liver damage by administering a specific dosage of *Morinda citrifolia* to a patient for the specific purpose of inhibiting the effects of carbon tetrachloride within the body of the patient, as does claims 1, 24, 27, and 31 of the present invention, as amended. Moreover, there is nothing in JP ‘686 that suggests the inhibition of carbon tetrachloride within a patient using a specific dosage of *Morinda citrifolia*.

Still further, applicant submits that the amounts administered by applicant are amounts that would not reasonably be arrived at by a person of ordinary skill in the art during a routine optimization of the disclosure of the reference. Indeed, applicant has included the limitation of at least two ounces in its claim for a specific reason. Upon careful and thorough clinical

experimentation, applicant has discovered the needed concentrations that are to be administered to a patient to effectuate inhibition of the effects or exposure of carbon tetrachloride within the patient. These concentrations are specifically recited in the specification and function to indicate that the amounts required for effective inhibition have been carefully derived. As JP '686 does not teach or suggest the claimed invention, as amended, applicant respectfully requests that the rejection be withdrawn.

Claims 1-22 and 24-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over WO 88/05304 (hereinafter "WO '304"). In response, applicant has amended claims 1 and 24 to recite a method of inhibiting hepatotoxin-induced liver damage by administering a specific dosage of *Morinda citrifolia* to a patient specifically for the purpose of inhibiting the effects of carbon tetrachloride within the body of the patient. In light of this amendment, applicant submits that WO '304 does not teach or suggest inhibition of hepatotoxin-induced diseases through the administration of *Morinda citrifolia*, wherein the *Morinda citrifolia* specifically does so by inhibiting the effects and exposure of carbon tetrachloride.

Moreover, applicant submits that WO '304 does not teach or suggest that the *Morinda citrifolia* is the ingredient that effectively inhibits the effects and/or exposure of carbon tetrachloride. Although WO '304 may include other ingredients, as may the composition of the present invention, the present invention specifically teaches that the ingredient *Morinda citrifolia* is relied upon to effectively inhibit hepatotoxin-induced diseases. Indeed, only through the administration of the ingredient *Morinda citrifolia* in its specified dosage can the effects of carbon tetrachloride be inhibited, as it is the ingredient *Morinda citrifolia* itself which is recited in the claims, as amended, as being capable of performing such a function. Such a specific

function is not taught or suggested in WO '304.

Finally, claims 1-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Number 4,039,559 (hereinafter "US '559") and U.S. Patent Application Number 2002/0068102 A1 (effective filing date December 1, 2000) (hereinafter "US Application '102"). In response, applicant submits that neither US '559 nor US Application '102, either individually or collectively, function to render obvious the claims of the present invention, as amended. Specifically, applicant submits that neither US '559 nor US '102 teach the specific concentrations of *Morinda citrifolia* and its ability to specifically inhibit the effects and exposure of carbon tetrachloride, as does the claims of the present invention, as amended. As stated above, the *Morinda citrifolia* concentrations are clinically tested to comprise the most optimal concentrations, in vitro, for effective inhibition of carbon tetra chloride within a patient. These in vitro concentrations are then interpolated to create a proper formulation of *Morinda citrifolia* for administration or ingestion by a patient and for effective inhibition of carbon tetrachloride. This proper formulation must comprise at least 2 ounces of processed *Morinda citrifolia*, as recited in the amended claims. Thus, the 1 ounce teaching in US '102 actually teaches away from the present invention. Moreover, although US '599 teaches that carbon tetrachloride causes liver damage, it does not teach or suggest that *Morinda citrifolia* itself is capable of inhibiting the effects of carbon tetrachloride. US '599 combined with US '102 does not teach this either. Claim 1 specifically requires a minimum of two ounces of *Morinda citrifolia* for effective treatment. The inclusion of these percentages is critical. As noted in "Example One" of the present invention, "the antioxidant activity of *Morinda citrifolia* shows a dose-dependant effect against superoxide anion radicals (SAR) and lipid hydroperoxides (LPO) *in vitro*."

The dosage limitation is not found, taught, or suggested in US '102, thus the two references combined cannot be said to be able to motivate one of ordinary skill in the art to arrive at the claims of the present invention.

In the absence of any suggestion or motivation to combine the above-referenced prior art, the mere fact that such prior art could be combined does not render the present invention obvious MPEP § 2142. As such, Applicant respectfully requests that the rejection be withdrawn.

### CONCLUSION

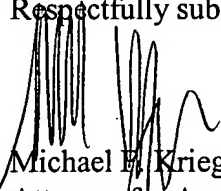
Applicant therefore respectfully submits that neither JP '686, WO '304, US '559, nor US Application '102 renders the claims of the present invention obvious as none of the references teach nor suggest the claims of the present invention. A withdrawal of the rejections made under Section 103(a) is therefore respectfully requested.

Based on the foregoing, Applicant believes that the claims of the present invention are in condition for allowance and respectfully requests the same.

Should the Examiner have any questions, comments, or suggestions in furtherance of the prosecution of this application, the Examiner is invited to initiate a telephone interview with undersigned counsel.

DATED this 29 day of December, 2003.

Respectfully submitted,

  
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